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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,889	12/15/2003	Elias Georges	112418-147 and AUR-013US	5738

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EXAMINER	
YAO, LEI	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/736,889	GEORGES ET AL.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *12-15-03*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-108* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-108* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-19, 59-74 drawn to a method for detecting multi-drug resistant (MDR) in a test neoplastic cells, a method for detecting multidrug resistance in a patient, a method for detecting a neoplastic cell, all methods comprising detecting a vimentin binding agent bound to cell-surface expressed vimentin, classified in class 435, subclasses 7.1, 7.23 and 7.8 and class 424, subclass 9.1.

II. Claims 20-42, 75-92, drawn to kits and an agent comprising a probe for the detection of vimentin and a cell surface vimentin targeted agent comprising a vimentin-binding component, classified in class 530, subclass 350 and 387.1.

III. Claims 43-48 and 93-98, drawn to a vaccine for treating or preventing a MDR neoplasm or neoplasm comprising vimentin polypeptide, classified in class 514, subclass 2.

IV. Claims 54-58 and 104-108, drawn to a method of treating or preventing a MDR neoplasm in a subject comprising administering a vimentin vaccine, classified in class 424, subclass 184.1.

V. Claims 49-53, 99-103, drawn to a method of treating or preventing a MDR neoplasm or neoplasm comprising administering a vimentin-targeted therapeutic agents to a subject, classified in class 424, subclass 187.1 and class 514, subclasses 2 and 21.

Inventions Group II and Group I/V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the kit/agent of Group II can be used to diagnosing neoplastic disease in vivo, as opposed to being used as detecting or treating neoplastic cell.

Searching the inventions of Groups II and I/V together would impose serious search burden. The inventions of Groups I and I/VI have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the detecting agents and the method of detecting neoplastic cells are not coextensive. Prior art, which teaches the composition of the kit or an agent, would not necessarily be applicable to the method of using the kit or agent. Moreover, even if the composition of kit or an agent were known, the method of detecting using the product may be novel and unobvious in view of the preamble or active steps.

Inventions Group III and Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case a method of treating or preventing of neoplasm of Group IV can be practiced by a protein or a nucleotides, as opposed to using the vaccines.

Searching the inventions of Groups III and IV together would impose serious search burden. The inventions of Groups III and IV have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the composition of a vaccine and the method of treating the disease with a vaccine are not coextensive. Prior art, which teaches the composition of a vaccine, would not necessarily be applicable to the method of using the vaccine. Moreover, even if the composition of a vaccine were known, the method of treating with the vaccine may be novel and unobvious in view of the preamble or active steps

The methods of Group I, IV, and V differ in the method objectives, method steps and parameters and in the reagents used. The instant specification does not disclose these methods would be used together. Group I is directed to detecting MDR in neoplastic cells by a kit or an agent, Group IV is directed to a method of treating or preventing a MDR neoplasm with a vaccine in a subject, whereas

Group V is directed to a method of treating or preventing a disease with an agent comprising a vimentin binding component.

Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for one group differ significantly from other groups. Therefore, each method is divergent in materials and steps. For these reasons the Inventions Group I, IV and V are patentably distinct.

Furthermore, the distinct method steps and products of invention Group I, IV and V have a separate status in the art as shown by their different classifications and require separate searches. Searching the inventions of Groups I, IV and V together would impose serious search burden. Prior art, which teaches method of detecting of MDR in neoplastic cells, would not necessarily be applicable to the method of treating or preventing the disease. Searching the method detecting of MDR in neoplastic cells is used only to determine the patentability of Group I not the others.

Election of species

This application contains claims directed to the following patentably distinct species of the claimed invention:

a. Neoplastic cells, drug sensitive cell line, or the tissue for neoplastic cells from claim 6, 7, 8, 9, 16, 17, 64, 65, 71, or 72) .
b. Vimentin binding agent, ligand from claim 12, 13, 23, 34, 35, 68, 69, 77, 84, or 85.
c. Detectable label from claim 14 or 70.

d. MDR markers from claim 21
e. MDR antibodies from claim 28.
f. Therapeutic components from claim 36, 37, 38, 39, 40, or 41 or 86, 87, 88, 89, 90, or 91.

g. Adjuvant form claim 48 or 98.

h. Neoplasm form claims 55, 105, 50, or 100.
i. Tissue for neoplasm form claims 58, 108, 53, or 103.

In the event that applicant elects **Group** I, applicant is required under 35 U.S.C. 121 to elect a single disclosed species from **a, b, and c** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the event that applicant elects **Group II,** applicant is required under 35 U.S.C. 121 to elect a single disclosed species from **d, e and f** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the event that applicant elects Group **III,** applicant is required under 35 U.S.C. 121 to elect a single disclosed species from **g** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the event that applicant elects **Group IV and V**, applicant is required under 35 U.S.C. 121 to elect a single disclosed species from **h and I** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitation of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. 821.04. Process claims that depend from or

otherwise include all the limitation of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that process claims should be amended during prosecution either to maintain dependency on the product claims or otherwise include the limitation of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.
Examiner
Art Unit 1642

LY

Karen A. Canella
KAREN A. CANELLA PH.D
PRIMARY EXAMINER